SZUTEST

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EC CERTIFICATE
AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System
Tam Kalite Güvencesi

Certificate Number: 2195-MED-1404201
Sertifika Numarası

Manufacturer:
Üretici

TRİA SPİNE MEDİKAL LTD. ŞTİ.
Head Office/Merkez: 1551. Sok. No:35 /33 İvedik OSB Yenimahalle ANKARA
Factory/Fabrika: 1551. Sok. No:35 /21 İvedik OSB Yenimahalle ANKARA

Product(s):
Ürün(ler)

Sterile LorX® Peek Cage System
Steril LorX® Peek Kafes Sistemi
Sterile LorX® Cervical Disc Prothesis
Steril LorX® Servikal Disk Protezi
Non Sterile PS® MINI Occipito-Cervico-Thoracic System
Steril Olmayan PS® MINI Occipito-Cervico-Thoracic Sistemi
Non Sterile PS® Cannulated Screw System
Steril Olmayan PS® Kanüllü Vida Sistemi
Non Sterile PS® Spine System
Steril Olmayan PS® Spinal Sistem
Non Sterile SPINE-S® Spine System
Steril Olmayan SPINE-S® Spinal Sistem
Non Sterile X-PS® Thoraco-Lumbar System
Steril Olmayan X-PS® Torako-Lomber Sistem

Reference Report No: MM0572-P002-R01, MM0572-P002-R02
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2020-09-01.
Bu AT Sertifikası 2020-09-01 tarihine kadar geçerlidir.

Issue Date/*Yayın Tarihi:* 2014-02-11
Revision No./ *Revizyon No.:* 03 Recertification/*Yeniden Belgelendirme*
Revision Date/ *Revizyon Tarihi:* 2017-09-02

Mehmet IŞIKLAR
General Manager
Genel Müdür

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Szutest Plaza Nato Yolu Cad. Çam Sok. No:7 Ümraniye 34775 İSTANBUL / TÜRKİYE
Szutest.com.tr

Certificate

TRIA SPINE MEDİKAL LTD. ŞTİ.

MUSTAFA KEMAL MH. 2141. SK. NO: 32/1 06520 ÇANKAYA – ANKARA – TURKEY

with a scope of

DESIGN, PRODUCT REALIZATION, SALES AND DISTRIBUTION OF NEUROSURGERY AND ORTHOPEADIC IMPLANTS

Medical devices - Quality management systems - Requirements for regulatory purposes

" Following elements of the standard are excluded "
"7.5.1.2.2" "7.5.1.2.3"

EN ISO 13485:2012

Certificate No	: M 10418
Initial Certification Date	: 08 June 2016
Certification Date	: 08 June 2016
Expiration Date	: 07 June 2019

General Manager

Kiwa Meyer Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören - Tuzla İstanbul – Türkiye
Tel: + 90 216 593 25 75 Fax : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: posta@meyer.gen.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 08 June 2016- R 00

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021
AB-0006-YS

EC-Certificate

SQS as a conformity assessment body identification number 1250 herewith certifies the company

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II — Directive 93/42/EEC (without section 4)

This approval is based on the result of the report dated September 18, 2017.

The scope of validity covers the products

Sterile and non sterile spine implants

The following CE label can be applied to the products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: October 8, 2017

This SQS Certificate is valid up to and including October 7, 2020
Registration number 33159
Approved Medical Responsible: September 25, 2017

R. Glauser, CEO SQS

K. Schulze, Medical Responsible

Trusted Cert

Swiss Made

Partner of IQNet

Appendix to the EC-Certificate

ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection
with the following certificate:

Registration Number 33159
Validity from October 8, 2017 up to and including October 7, 2020

This approval includes the following Medical Devices:

Class IIb
TRYPTIK® 2 C-Plate Anterior Cervical Plate System and the associated instrumentation
Cervical cage MOSAIKca range
Cervical cage modular MOSAIKmc, MOSAIKmp, MOSAIKcs range
Cervical plate MOSAIKpl range
Lumbar osteosynthesis ELLIPSE range
Lumbar osteosynthesis ROMEO range and associated instrumentation ROMEO2 and ROMEO2 MIS
Lumbar cage DYNAMIKpo range
Lumbar cage DYNAMIKan range
Lumbar cage JULIETpo range
Lumbar cage JULIETan range
JULIET®LL and JULIET®LL-T lateral lumbar cage range and the associated instrumentation
Cervical disc prosthesis BAGUERAc range
Intersomatic cervical cage TRYPTIKca, TRYPTIKcc and the associated instrumentation TRYPTIKin
Intersomatic cervical modular cage TRYPTIKmc, modular plate TRYPTIKmp and cervical screw TRYPTIKcs
Cervical plate TRYPTIKpl
Disc prosthesis BAGUERA L and the associated instrumentation
Intersomatic lumbar cage DYNAMIKtl and the associated instrumentation
Intersomatic lumbar cage JULIETtl and the associated instrumentation
Cervical Staple TRYPTIK lamina and the associated instrumentation
Cervical cage SCARLET® AC-T range and the associated instrumentation
TRYPTIKca pre-filled cage range
TRYPTIKcc pre-filled cage range
TRYPTIKmc pre-filled cage range
DYNAMIKpo pre-filled cage range
DYNAMIKan pre-filled cage range
DYNAMIKtl pre-filled cage range
JULIETpo pre-filled cage range
JULIETan pre-filled cage range
JULIETtl pre-filled cage range
JULIETol pre-filled cage range
SCARLET® AC-T pre-filled cage ranges
Intersomatic Lumbar Cage JULIET ol and the associated instrumentation
Posterior axial device ROMEO2 PAD range and the associated instrumentation
Intersomatic lumbar cage JULIET Ti PO
Intersomatic lumbar cage JULIET Ti OL
Intersomatic lumbar cage JULIET Ti TL

Class IIa
Single use surgical instruments STERILE packaged
Vertebral body elevation TEKTONA instrumentation range

Appendix issue date: October 8, 2017

DECLARATION OF CONFORMITY

DECLARATION DE CONFORMITE

We, SPINEART SA, Chemin du Pré-Fleuri 3, 1228 PLAN-LES-OUATES, Switzerland

Nous, SPINEART SA, Chemin du Pré-Fleuri 3, 1228 PLAN-LES-OUATES, Suisse

Declare under our own responsibility that the products:

Déclarons sous notre seule responsabilité que les produits :

Cervical Disc Prosthesis, BAGUERA®C

(Implantable devices)

Prothèse de disque cervicale, BAGUERA®C

(Dispositifs implantables)

Are designed, developed, manufactured and distributed in accordance with a QMS that is conform to the EN ISO 13485 standard as well as to other standards or regulatory documents as mentioned in the Design History File n°16.

Sont conçus, développés, fabriqués et distribués en accord avec un SMQ conforme à la norme EN ISO 13485 et autres documents normatifs et réglementaires énoncés dans le Dossier de Conception n°16.

In conformity with the European Directive n° 93/42/EEC related to Medical Devices

Conforme aux dispositions de la Directive Européenne n° 93/42/CEE relative aux dispositifs médicaux

- **Implant, Class IIb in accordance with Annex II (excluding section 4), classification accordingly to Annexe IX rule 8,** *Implant de Classe IIb selon Annexe II (exclue section 4), classification définie selon Annexe IX règle 8,*

Based on the CE certificate n° 33159 issued by the notified body:

Sur la base du certificat CE n° 33159 délivré par l'organisme notifié :

SQS

Swiss Association for
Quality and Management System
Bernstrasse 103, CH-3052 Zollikofen

CE 1250

Under registration number :

Sous le numéro d'identification :

Plan-les-Ouates, October 9th, 2017

Plan-les-Ouates, le 9 octobre 2017

Quality / RA Director,
Directeur qualité / AR
Mr Franck PENNESI

SPINEART SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
N° Fédéral : CH 660-1013005-1
N° TVA : CHE – 112.355.249
www.spineart.com

This declaration of conformity is valid until: October 2nd, 2020

Cette déclaration de conformité est valable jusqu'au : 2 octobre 2020

DECLARATION OF CONFORMITY

DECLARATION DE CONFORMITE

Reference	Description	Classification *Acc. to 93/42/EEC*
	Cervical Disc Prosthesis BAGUERA c	
	Sterile	
CDP-TI 13 05-S	Cervical Disc Prosthesis BAGUERA c *D13 W16 H05*	Class IIb
CDP-TI 13 06-S	Cervical Disc Prosthesis BAGUERA c *D13 W16 H06*	Class IIb
CDP-TI 13 07-S	Cervical Disc Prosthesis BAGUERA c *D13 W16 H07*	Class IIb
CDP-TI 14 05-S	Cervical Disc Prosthesis BAGUERA c *D14 W17 H05*	Class IIb
CDP-TI 14 06-S	Cervical Disc Prosthesis BAGUERA c *D14 W17 H06*	Class IIb
CDP-TI 14 07-S	Cervical Disc Prosthesis BAGUERA c *D14 W17 H07*	Class IIb
CDP-TI 16 05-S	Cervical Disc Prosthesis BAGUERA c *D16 W18 H05*	Class IIb
CDP-TI 16 06-S	Cervical Disc Prosthesis BAGUERA c *D16 W18 H06*	Class IIb
CDP-TI 16 07-S	Cervical Disc Prosthesis BAGUERA c *D16 W18 H07*	Class IIb

Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

Scope of certification

According to appendix

Field of activity

Design, manufacturing and sales of sterile and non-sterile spine medical devices

Normative base

EN ISO 13485:2016 Medical devices – Quality Management System

Validity 03. 10. 2017 – 02. 10. 2020
Issue 27. 06. 2018

Reg. no. H31786

X. Edelmann, President SQS

R. Glauser, CEO SQS

sqs.ch

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland

Swiss Made

Partner of IQNet

Appendix

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

Central Function	*Field of activity*	*Scope(s)*	*Norm / Revision*	*Reg. no.*	*Validity*
Spineart SA Chemin du Pré-Fleuri 3 1228 Plan-les-Ouates Switzerland	Design, manufacturing and sales of sterile and non-sterile spine medical devices	19	EN ISO 13485:2016	H31786	03.10.2017 02.10.2020

Locations	*Field of activity*	*Scope(s)*	*Norm / Revision*	*Reg. no.*	*Validity*
Alpes CN SAS Bâtiment ABC3 Archamps Technopole 80, Rue Douglas Engelbart 74160 ARCHAMPS France	Control, assembly, cleaning and packaging of Spineart Medical Devices in clean room	19	EN ISO 13485:2016	H31786	27.06.2018 02.10.2020
SLI SAS Bâtiment ABC3 Archamps Technopole 80, Rue Douglas Engelbart 74160 ARCHAMPS France	Maintenance activity of Spineart instrumentation, logistic and storage management of Spineart Medical Devices	19	EN ISO 13485:2016	H31786	27.06.2018 02.10.2020

X. Edelmann, President SQS

R. Glauser, CEO SQS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 09 58603 048

Manufacturer:

aap Biomaterials GmbH
Lagerstrasse 11-15
64807 Dieburg
GERMANY

Facility(ies):

aap Biomaterials GmbH
Lagerstrasse 11-15, 64807 Dieburg, GERMANY

aap Biomaterials GmbH
Nordring 29, 64807 Dieburg, GERMANY

Product Category(ies):

Mixing and delivery devices for bone cements and sterile accessories (class IIa)
bone substitute materials (class III)
and bone cements (class IIb + class III)

The Certification Body of TÜV SÜD Product Service GmbH 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 subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713061786

Valid from: 2015-10-24
Valid until: 2020-10-23

Date, 2015-09-29

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04.11

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

PAJUNK GmbH Medizintechnologie

Karl-Hall-Straße 1, 78187 Geisingen, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 51268-Z2-00, the decision dated 2015-03-20 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 2010-03-22 Date of the last recertification: 2015-03-22

This certificate is valid until: 2020-03-21 Certificate registration No.: 51268-16-01

DEKRA Certification GmbH
Stuttgart, 2015-03-20
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-295.10.02

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid.

Annex to the EC Certificate 51268-16-01 dated 2015-03-20

Devices/device categories included in the certificate

Class II a (non-active):

Cannulas, special cannulas and kits (treatment units) for peripheral regional anesthesia: Stimulation cannulas, special cannulas and kits for peripheral regional anesthesia with position verification via electric impulse

Single components (Split cannula, permanent cannula, introducer- and initial puncture cannulas, stylets, obturator needles, injection syringes, injection tubes, adapter, stimulation adapter, injektion Y-tube, filter, injection cannulas, scalpels, extracorporal fixations and kits for

a) regional anesthesia with optional positional verification via electric impulse
b) common surgical supply

Cannulas, Special cannulas, treatment units, systems for puncture, aspiration and section for histology (biopsy) of soft tissue and bone / bone marrow

Cannula for intravenous and intra-arterial (vascular) puncturing

Cannula for endocenous therapy

Dilators, obturators, balloons for dilation, balloons and trocars, trocar sleeves, valves for fixation for preparation of surgical and minimal-invasive interventions in the field of urology, gynecology, laparoscopy (hysteroscopy, arthroscopy), histology (biopsy)

Valves, modular instruments (handles, tubes, insert), endoscopes and optics for surgical and minimal-invasive interventions in the field of urology, gynecology, laparoscopy (hysteroscopy, arthroscopy), histology (biopsy)

Y-tubes and devices as well as accessories (three-way-stopcock, connection cable), Switchbox for ECG-monitoring

Transjugular intrahepatic portosystemic shunt

Bolus cannulas, two-way-stopcock, perfusion syringe, stericlin bag within the scope of longterm analgesia

Cannulas, three-way-stopcock, surgical bag, catheter for general surgery

Cannulas, special cannulas and treatment units for common hospital supply for use according to physicians indication

Tube, cannulas, syringe and adapter for aerosole local anesthesia of the respiratory system/ the trachea

Cannulas for positioning/ implantation of radioisotopic seeds within the scope of the oncology

Cannulas, special cannulas, treatment units, catheters and forceps for punction, aspiration, section and injection of contrast medium, for example for cholangiography (X-ray of the biliary tract with contrast medium), for mammography and galactography, PTC, not contacting CSF/ CNS

Cannula for surgical therapy of VUR (VESICO URETERAL REFLUX)

(orthopedic) instrument for creation of cavum

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

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

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

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

HumanTech Spine GmbH

Gewerbestrasse 5
71144 Steinenbronn
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Cervical Plate Screw Fixation System	class IIb
Spinal Screw Rod Fixation System	class IIa and IIb
Anterior Cervical Interbody Devices	class IIa and IIb
Lumbar Interbody Devices	class IIb
Cement Applicator	class IIa
Vertebral Body Replacement Devices	class IIb

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	540287 MR2
Certificate unique ID	170727894
Effective date	2018-11-01
Expiry date	2023-10-31
Frankfurt am Main	2018-11-01

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

| evaluate | assess | certify |

assessors of quality

Management System Certificate

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

This is to certify that

Samay Surgicals

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

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

ISO 13485:2016

This certificate is valid for the following scope :

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

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

Authorised Signatory

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

Zenith Quality Assessors Pvt. Ltd.
(Management System Certification Division, MSCD002)
306, 4th Floor, Sai Apex, Near Datta Mandir, Viman Nagar, Pune - 411 014, Maharashtra, India.
www.zenith-worldwide.com

Accreditation Body : ACCREDITATION SERVICE FOR CERTIFYING BODIES (EUROPE) Ltd.
6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.
www.ascb.co.uk

C/ASCB/MDQMS16/00/121216 (Cl.8.2)