

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

**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 report dated January 6, 2020.

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.

Reg. no. 33159

Validity 24.01.2020–25.05.2024  
Issue 24.01.2020

Approved Medical Responsible  
24.01.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



## 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 January 24, 2020 up to and including May 25, 2024

### This approval includes the following Medical Devices:

Class IIb

TRYPTIK 2 C-Plate Anterior Cervical Plate System

Lumbar osteosynthesis ROMEO2 range

Lumbar osteosynthesis ROMEO2 MIS (Minimal Invasive Surgery)

Lumbar cage JULIETpo PEEK

Lumbar cage JULIETan PEEK

JULIET LL PEEK and JULIET LL-T lateral lumbar cage

Cervical disc prosthesis BAGUERAc range

Intersomatic cervical cage TRYPTIKca and TRYPTIKcc

Intersomatic cervical modular cage TRYPTIKmc, modular plate TRYPTIKmp and cervical screw TRYPTIKcs

Cervical cage SCARLET AC-T range

Intersomatic lumbar cage JULIETtl PEEK

Intersomatic lumbar cage JULIETol PEEK

Intersomatic lumbar cage SCARLET AL-T

Posterior axial device ROMEO2 PAD range

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

Appendix Issue: January 24, 2020

