EC-Certificate

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 instruments

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. 45886

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

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

Swiss Made

Partner of IQNet

sqs.ch

4174_2/June 2019/Version 2.0

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 45886

Validity from January 24, 2020 up to and including May 25, 2024

This approval includes the following Medical Device/s:

Classe IIa
Vertebral body elevation TEKTONA instrumentation range

Appendix Issue: January 24, 2020

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Swiss Association for Quality
and Management Systems (SQS)
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