

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 660614  
**Issued To:** **NovaSpine S.A.S.**  
**335, rue Saint Fuscien**  
**Amiens**  
**80090**  
**France**

In respect of:

**The design, development and manufacture of posterior spinal fixation system used from occipital to sacro iliac segment, lateral spinal fixation system used in thoraco lumbar segment, anterior cervical osteosyntheses implants, cervical and lumbar interbody fusion implants, lumbar interspinous implants, total anterior cervical disc replacement implants all for end user sterilisation**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2017-10-10**

Date: **2019-01-11**

Expiry Date: **2020-12-21**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Acnis International 220 Rue Léon Blum Villeurbanne 69100 France	<b>Crucial Supplier</b>
Charles PERY & Cie s.a.s. 360, Avenue du Stade B.P. 27 Scionzier CEDEX 74951 France	<b>Manufacture</b>
Invibio Ltd. Invibio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	<b>Crucial Supplier</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Novaspine SAS 10, rue Clement Marot Salouel 80480 France	<b>Design</b> <b>Manufacture</b>
STAINLESS 4 rue Thalès Dannmarie-sur-Crete 25410 France	<b>Crucial Supplier</b>
Zapp Precision Metals GmbH Letmather Straße 69 Schwerte 58239 Germany	<b>Crucial Supplier</b>

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## Certificate History

Certificate No: **CE 660614**  
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Date	Reference Number	Action
10 October 2017	8593041	First issue Transfer from another Notified Body.
Current	8859620	Traceable to NB 0086.

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