

# 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, anterior cervical osteosyntheses implants, cervical and lumbar interbody fusion implants, lumbar interspinous implants, total anterior cervical disc replacement implants all for end user sterilization**

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):



Gary E Slack, Senior Vice President Medical Devices

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

Date: **2020-12-22**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 660614

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
61325	SOCORE Posterior Spinal fixation system from occipital to sacro iliac segment: Monoaxial/Polyaxial screws, Rods, Crosslinks, Hooks, connectors, occipital plate and screws.	Used for the treatment of spinal pathologies to stabilize two or more vertebrae of the spine and help achieve fusion. Used from occipital to sacro iliac segment.
46651 46653 57805 57806 60762	DIVA Cervical interbody fusion implants: Cervical cage, plate and screw	Used for inter-somatic stabilization of two or more vertebral bodies of the spine to help achieve fusion. Used in cervical spine.
46651 46653 57805 60762	DIVA Lumbar interbody fusion implants: Lumbar fusion cage, plate and screw	Used for inter-somatic stabilization of two or more vertebral bodies of the spine to help achieve fusion. Used in lumbar spine.

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Number	Device Name	Intended purpose per IFU
61532	RODD Lumbar interspinous implants	Used in inter spinous space to restore the height, stabilize and keep the physiological movement of the spine without fusion. Used in lumbar spine.
46653 46651	MATRIS Cervical osteosynthesis	Used in cervical area to stabilize two or more vertebrae of the spine and help achieve fusion.
46653 46651 61865	ALMAS Cervical total disc replacement	Used in inter somatic space to restore the height, stabilize and keep the physiological movement of the spine without fusion. Used in Cervical spine by anterior approach.

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

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# EC Certificate - Full Quality Assurance System

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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Subcontractor:	Service(s) supplied
ACNIS INTERNATIONAL 17, Rue des Frères Lumière Chassieu 69680 France	Crucial Supplier
ATI 1600 Old Salem Road NE Albany OR 97321 USA	Crucial Supplier
ATI 3101 Kingsgate Way Richland WA 99354 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
ATI 530 34th Ave SW Albany OR 97322 USA	Crucial Supplier
ATI 7400 Highway 20 West Huntsville AL 35806 USA	Crucial Supplier
BOHLER EDELSTAHL Mariazelerstraße 25 8605 Kapfenberg Austria	Crucial Supplier
CARPENTER 101 west bern street Reading, PA 19601 USA	Crucial Supplier

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### Subcontractor:

### Service(s) supplied

Charles PERY & Cie s.a.s.  
 360, Avenue du Stade B.P. 27  
 Scionzier CEDEX  
 74951  
 France

**Manufacture**

Daido Steel  
 Shibukawa Plant  
 500, Ishihara  
 Shibukawa-shi  
 Gunma  
 377-0007  
 Japan

**Crucial Supplier**

Daido Steel Co. Ltd  
 Hoshizaki Plant  
 30, Daido-cho 2-chome, Minami-ku  
 Nagoya, Aichi  
 457-8545  
 Japan

**Crucial Supplier**

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### Subcontractor:

### Service(s) supplied

Dynamet Inc.  
 195 Museum Road  
 Washington  
 Pennsylvania  
 15301  
 USA

**Crucial Supplier**

Forecreu  
 20 bis, Rue du Vieux Bourg  
 COMMENTRY  
 03600  
 France

**Crucial Supplier**

Fort Wayne Metals  
 9609 Ardmore Avenue  
 Fort Wayne  
 IN 46809  
 USA

**Crucial Supplier**

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Subcontractor:	Service(s) supplied
HUB MEDICAL Rue Moussa Ibn Noussair ZI 2 Grombalia 8030 Tunisia	Manufacture
Invibio Ltd. Invibio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	Crucial Supplier
Novaspine SAS 10, rue Clement Marot Salouel 80480 France	Design Manufacture

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Subcontractor:	Service(s) supplied
PERRYMAN 213 vandale drive Houston PA 15342 USA	Crucial Supplier
STAINLESS 4 rue Thalès Dannmarie-sur-Crete 25410 France	Crucial Supplier
TiFast S.r.l Zona Industriale San Liberato 05035 Narni (TR) Italy	Crucial Supplier
TIMET - TITANIUM METALS CORPORATION 181 North Water Street Gate 3 Black Mountain Industrial Park Henderson NE 89015 USA	Crucial Supplier

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**Subcontractor:****Service(s) supplied**

TIMET Savoie  
62, Avenue Paul Girod  
UGINE  
73400  
France

**Crucial Supplier**

TIMET UK Ltd  
PO Box 704  
Holford Drive  
Witton  
Birmingham  
B6 7UR  
United Kingdom

**Crucial Supplier**

ULBA METALLURGICAL PLANT SCC  
102 Abay Avenue  
Ust-Kamenogorsk  
070005  
Republic of Kazakhstan

**Crucial Supplier**

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Subcontractor:	Service(s) supplied
VSMPO-Tirus US Pittsburgh 401 Riverport Drive Leetsdale PA 15056 USA	Crucial Supplier
VSMPO-Tirus US California 2850 E. Cedar Street Ontario CA 91761 USA	Crucial Supplier
Zapp Precision Metals GmbH Letmather Straße 69 Schwerte D-58239 Germany	Crucial Supplier

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Date	Reference Number	Action
10 October 2017	8593041	First issue. Transfer from another Notified Body.
11 January 2019	8859620	Traceable to NB 0086.
12 September 2019	9665364	Addition of Crucial suppliers: FORECREU, France; TIMET, France, UK and NE, USA; DYNAMET Inc., PA, USA; ULBA METALLURGICAL PLANT SCC, Kazakhstan; Daido Steel, Japan; ATI, AL, OR and WA, USA; PERRYMAN, PA, USA; Fort Wayne Metals, IN, USA; CARPENTER, PA, USA; BOHLER EDELSTAHL, Austria. Update of ACNIS INTERNATIONAL address

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Date	Reference Number	Action
19 November 2020	9759532	Removal of SOCORE thoraco lumbar spinal fixation system (product codes SSSR82, SSSL83, STSR84, STSL85, SLSR86, SLSL87). Reduction of scope to removal lateral spinal fixation system used in thoraco lumbar segment. Removal of DIVA lumbar corpectomy cages (product codes DCL01T, DCL02T, DCSL01T, DCSL02T, DCL01 - 03, DCSL01 - 03) Update of DIVA range IFU (removal of lumbar corpectomy indications) Addition of critical subcontractor HUB MEDICAL for the activity of Manufacture Addition of Crucial suppliers: TIFAST (Italy), VSMPO-Tirus (PA & CA).
Current	9768161	Certificate renewal Add product table

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