

EC Certificate - Full Quality Assurance System

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

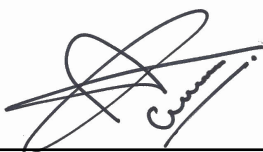
No. CE 632519
Issued To: **SURGIVAL co. S.A.U.**
Leonardo Da Vinci 12-14
Paterna
Valencia
46980
Spain

In respect of:

The design and manufacture of screws, washers, nuts, bolts, staples, plates, nails, wires and pins for osteosynthesis, intramedullary nails for hip femoral head fractures, dynamic hip/condylar compression screw-plate systems, hip hemi-arthroplasty prosthesis and accessories for total knee replacement prosthesis

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: **2015-04-28**

Date: **2019-03-04**

Expiry Date: **2022-02-24**

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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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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 220 Rue Léon Blum Villeurbanne 69100 France	Crucial Supplier
Aragogamma S.L Ctra. Granollers a Cardedeu, Km 3.5 Les Franqueses del Vallés Barcelona 08520 Spain	Gamma Sterilization
ASIATORR Olasope nº3 Elgoibar 20870 Spain	Crucial Supplier

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Subcontractor:	Service(s) supplied
Cartolux Thiers SAS ZI les torrents Peschadoires 63920 France	Crucial Supplier
DBP Aquitaine ZAE Eyrialis Le Barp 33114 France	Manufacture
EZM Auestrasse 4 Witten 58452 Germany	Crucial Supplier

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Subcontractor:	Service(s) supplied
Forecreu 20 bis, Rue du Vieux Bourg COMMENTRY 03600 France	Crucial Supplier
Laser Manufacturing Pol Ind Ciutat de Carlet Carlet Valencia 46240 Spain	Crucial Supplier
Microsteel-CIMD 3, rue de Plessis Vern-sur-seiche 35770 France	Crucial Supplier

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Subcontractor:	Service(s) supplied
Microsteel-CIMD ZA des grands Sillons Corps Nuds 35150 France	Crucial Supplier
Orchid Orthopaedic Solutions Parkway Close Parkway Industrial Estate Sheffield South Yorkshire United Kingdom	Crucial Supplier
SANDVIK Materials Technology EMEA AB Färögatan 7 Kista 16493 Sweden	Crucial Supplier

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Subcontractor:	Service(s) supplied
SUDPACK Médica ZA de Beaumont Nord Coulmer Grace 61230 France	Crucial Supplier
VILARDELL PURTI S.A. Pol. Ind. Santa Anna I Santpedor Barcelona 08251 Spain	Manufacture
Zapp Precision Zapp-Platz 1 Ratingen 40880 Germany	Crucial Supplier

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
28 April 2015	8295206	First Issue, Transfer from another Notified Body.
24 February 2017	8663800	Certificate renewal. Addition of the following subcontractors: Laser Manufacturing, Pol Ind Ciutat de Carlet 46240 Carlet, Valencia, Spain; ASIATORR, Olasope nº3 20870 Elgoibar, Spain; SUDPACK Médica, ZA de Beaumont Nord, Coulmer FR 61230 Grace, France; Forecreu, 20 bis, rue du Vieux Bourg, Commentry, 03600 France; SANDVIK Materials Technology EMEA AB, Färögatan 7, 16493 Kista, Sweden; Microsteel-CIMD, 3, rue de Plessis, 35770 Vern-sur-seiche, France; Microsteel-CIMD, ZA des grands Sillons, 35150 Corps Nuds, France; Orchid Orthopedic Solutions, Parkway Close, Parkway Industrial Estate, Sheffield, South Yorkshire, United Kingdom; Acnis International, 220 Rue Léon Blum, 69100 Villeurbanne, France; Zapp Precision, Zapp-Platz 1, 40880 Ratingen, Germany; EZM, Auestrasse 4, 58452 Witten, Germany; Cartolux Thiers SAS, ZI les torrents, Peshadoires, 63920, France.
Current	8630137	Traceable to NB 0086.