By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 639319**

Issued To: **EUROS SAS**
Z.E Athélia III
LA CIOTAT
13600
France

In respect of:

The Design, Development and Manufacture of sterile and non-sterile: total joint replacements; hip hemi arthroplasty femoral heads; modular acetabular reinforcement system; bone fixation screws for hip, knee and shoulder components; osteosynthesis implants for foot and ankle joints; internal fixation system for thoracolumbar spinal osteosynthesis; spinal intervertebral fusion devices; spinal cervical plates and screws; and associated non-sterile trials and instruments connecting to active devices.
Those aspects of Annex II related to securing and maintaining metrology, in the manufacture of the Spinal Measuring Instrumentation.

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: **2016-01-19** Date: **2019-02-07** Expiry Date: **2023-02-12**

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List of Significant Subcontractors

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

Certificate No:	**CE 639319**
Date:	**2019-02-07**
Issued To:	**EUROS SAS** **Z.E Athélia III** **LA CIOTAT** **13600** **France**

Subcontractor:	**Service(s) supplied**
A.M.F. Route de Quincy Lury Sur Arnon 18120 France	**Manufacture**
Acnis International 220 Rue Léon Blum Villeurbanne 69100 France	**Crucial Supplier**
AK Steel 2-6 rue des Bourets Suresnes 92150 France	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
ATS ZI de Bruèges, Avenue Monge BP 80286 ALES CEDEX 30106 France	**Manufacture**
CeramTec GmbH Medical Products Division CeramTec Platz 1-9 73207 Plochingen Germany	**Manufacture**
COULOT 1 Rue Nungesser et Coli CHATELLERAULT 86100 France	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Ets Marle SAS BP 46, ZI rue Lavoisier Nogent 52800 France	**Manufacture**
Forecreu 20 bis, Rue du Vieux Bourg COMMENTRY 03600 France	**Crucial Supplier**
Früh Verpackungstechnik AG Allmendstrasse 47 Fehraltorf 8320 Switzerland	**Packaging**

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Subcontractor:	**Service(s) supplied**
Haute Marne Parachèvement 4 Cité Artisanale Henri Voirpy Sarrey 52140 France	**Manufacture**
HTI TECHNOLOGIES 49, Avenue Franklin Roosevelt DECINES 69150 France	**Other Critical Processes**
Invibio Ltd. Invibio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
LISI Medical 19 Chemin de la Traille - Neyron MIRIBEL 01700 France	**Manufacture**
Lisi Medical Orthopaedics 203 Bd de la Grande Delle - BP 8 Herouville-Saint Clair Cedex 14201 France	**Manufacture**
Marle Finishing SAS 22 rue de la Mollanche Sorbiers 42290 France	**Manufacture**

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Subcontractor:	**Service(s) supplied**
MediTech Medical Polymers Division of Quadrant EPP Max-Plantstraße 11 Vreden 48691 Germany	**Crucial Supplier**
Micro-Tolerie Dallard 64, Chemin Ferrat ZI Les Reys de Saulce Saulce sur Rhône 26270 France	**Crucial Supplier**
Nowak 6 Rue du Bélier PANCE 35320 France	**Manufacture**

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Subcontractor:	**Service(s) supplied**
PROJECTION PLASMA SYSTEME (2PS) ZI du Colombier BP 4 MONTBAZENS FR-12220 France	**Other Critical Processes**
Sferic ZA Rue du Courtois prolongée Menars 41500 France	**Manufacture**
STAINLESS 2 Rue Thalès DANNEMARIE SUR CRETE 25410 France	**Crucial Supplier**
Synergy Health Marseille SAS MIN 712 Les Arnavaux 13323 Marseille Cedex 14 France	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
TeroLab Surface SAS ZI - rue Jean-Pierre Timbaud Villeneuve Le Roi 94290 France	**Other Critical Processes**
TIMET The Hub Holford Road off Witton Road Birmingham B6 7BJ United Kingdom	**Crucial Supplier**
Wichard Zone Industrielle de Felet CS 50085 FR-63307 THIERS CEDEX France	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
19 January 2016	8374096 8455424	First issue. Transfer from another Notified Body. Renewal.
21 February 2017	8631103	Clarification to scope and extension to scope following a transfer from another Notified Body. Addition of the significant subcontractors A.M.F and AK Steel. Correction to certificate expiry to match transferred certificate.
07 February 2018	8666523	Extension to scope to include total joint replacements. Reduction in scope to exclude osteosynthesis femoral screws. Addition of critical subcontractors ATS SAS, CeramTec, Haute Marne Parachèvement, HTI Technologies, LISI Medical Orthopaedics, Ets Marle SAS, Marle Finishing SAS, SFERIC, Wichard, Projection Plasma Systeme and TeroLab Surface SAS. Addition of crucial supplier MediTech Medical Polymers.
21 February 2018	8844076	Certificate renewal. Removal of the subcontractor UND, clarification of activities for Wichard (Crucial Supplier).
Current	8713293	Traceable to NB 0086.