

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

**AMPLITUDE**

11 Cours Jacques Offenbach  
ZA Mozart 2  
VALENCE  
26000  
France

Holds Certificate Number:

MD 615264

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, manufacturing and distribution of orthopaedic/joint implants, surgical instruments and computer assisted surgery systems.

*Stewart Brain*

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-04-25

Latest Revision Date: 2017-05-09

Effective Date: 2017-05-03

Expiry Date: 2019-02-28

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies

Certificate No: MD 615264

Location

Registered Activities

AMPLITUDE  
11 Cours Jacques OFFENBACH  
ZA Mozart 2  
VALENCE  
26000  
France

Design, manufacturing and distribution of orthopaedic/joint implants, surgical instruments and computer assisted surgery systems.

AMPLITUDE (Neyron)  
Porte du Grand Lyon  
Bât A  
NEYRON  
01700  
France

Distribution

AMPLITUDE  
43 cours Manuel de Falla  
VALENCE  
26000  
France

Warehouse

Original Registration Date: 2015-04-25

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# EC Certificate - Full Quality Assurance System

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

No.

**CE 615308**

Issued To:

**AMPLITUDE  
11 Cours Jacques OFFENBACH  
ZA Mozart 2  
VALENCE  
26000  
France**

In respect of:

**Design, development and manufacture of: hip joint replacement and hemi-hip arthroplasty devices, knee joint replacement devices, osteosynthesis implants, and associated trial prostheses, instruments connecting to active devices and accessories; Computer assisted surgery systems.**

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 0086):



Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2015-04-27**

Date: **2018-03-15**

Expiry Date: **2022-05-02**

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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.  
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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:

Certificate No: **CE 615308**  
 Date: **2018-03-15**  
 Issued To: **AMPLITUDE**  
**11 Cours Jacques OFFENBACH**  
**ZA Mozart 2**  
**VALENCE**  
**26000**  
**France**

Subcontractor:	Service(s) supplied
Acnis International 220 Rue Léon Blum Villeurbanne 69100 France	Crucial Supplier
ATS SAS ZI de Bruèges Avenue Monge BP 80286 Ales Cedex 30106 France	Crucial Supplier Manufacture
Belmonte ZAC des couleurs Chemin du Pau Valence 26000 France	Manufacture



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**26000**  
**France**

Subcontractor:	Service(s) supplied
Ceramtec CeramTec GmbH Medical Products Division CeramTec Platz 1-9 Plochingen 73207 Germany	Manufacture
DOT GmbH Charles-Darwin-Ring 1 a Rostock 18059 Germany	Other Critical Processes
ENTEGRIS 395, rue Louis Lépine MONTPELLIER 34000 France	Assembly Other Critical Processes Packaging



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**France**

Subcontractor:	Service(s) supplied
Eurocoating Via al DOS De La Roda, 60 Pergine Valsugana 38057 Italy	Other Critical Processes Packaging
Firm Industrie ZA Blacheronde d'Etoile Etoile Sur Rhone 26800 France	Manufacture
HTI TECHNOLOGIES 49, Avenue Franklin Roosevelt DECINES 69150 France	Other Critical Processes



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**France**

Subcontractor:	Service(s) supplied
Invio Ltd. Invio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	Crucial Supplier
Marle ZI rue Lavoisier Nogent 52800 France	Crucial Supplier Manufacture
Marle Finishing SAS 22 rue de le Mollanche Sorbiers 42290 France	Manufacture Other Critical Processes Packaging



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**France**

Subcontractor:	Service(s) supplied
Marle Finishing SAS 443 Rue René Cassin La Talaudière 42350 France	Manufacture
MediTECH Medical Polymers Division of Quadrant EPP 2710 American Way Ft. Wayne Indiana 46809 USA	Manufacture
Microweld Parc Altaïs, Rue Uranus CHAVANOD 74650 France	Other Critical Processes



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**France**

Subcontractor:	Service(s) supplied
Poli Alpes 12, rue Laurent de Lavoisier Portes Les Valence 26800 France	Surface Treatment
Poli-Tech' ZA Blacheronde d'Etoile Etoile Sur Rhone 26800 France	Surface Treatment
Progress Silicones ZI des Bourguignons APT 84400 France	Crucial Supplier



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**France**

Subcontractor:	Service(s) supplied
S.A.R.L. Devise 6 impasse Aulagnier Portes Les Valence 26800 France	Crucial Supplier
Serret Mecanique 185 Allee De L'Hermitage - Zone Industrielle SUD Bourg De Peage 26300 France	Crucial Supplier
Simagec 54 Avenue de la Plaine Rousset 13106 France	Assembly Other Critical Processes Packaging



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**26000**  
**France**

Subcontractor:	Service(s) supplied
Societe Mecanique Pansu Quartier de Brezide Beaumont Les Valence 26760 France	Crucial Supplier
STAINLESS 4 rue Thalès Dannmarie-sur-Crete 25410 France	Crucial Supplier
SYNERGY HEALTH MARSEILLE Entrepot Min 712 Les Arnavaux MARSEILLE 13014 France	Gamma Sterilization



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**26000**  
**France**

Subcontractor:	Service(s) supplied
UDT Meca ZI Les Auréas 5 allée Bernard Palissy Valence 26000 France	Crucial Supplier
VIT RESSORT ZA le Boutariq Rue du Pic de Bure Veynes 05400 France	Crucial Supplier
Westlake Plastics Europe SAS 159 rue de Rotterdam ZAC Ravennes les Francs Bondues 59910 France	Crucial Supplier



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# EC Certificate - Full Quality Assurance System

## Certificate History

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**France**

Date	Reference number	Action
27 April 2015	8165223	First Issue - Transfer from another Notified Body
08 July 2015	8291732	Extension to scope to include the Trial Prostheses Class IIa devices
09 May 2017	8712742	Certificate Renewal Clarification of scope Addition of significant subcontractors and crucial suppliers: HTI Technologies, MediTECH Medical Polymers (Division of Quandrant EPP), Microweld, Progress Silicones, Stainless and Westlake Plastic Europe SAS Removal of significant subcontractors: MEDICAL Group CORP, MEDIMET and QUADRANT
Current	8906823	Addition of significant subcontractors and crucial suppliers: Poli-Tech', Belmonte, Firm Industrie, Marle Finishing SAS (22 Rue de la Mollanche & 443 Rue rené Cassin), Poli Alpes, UDT Meca, Societe Mecanique Pansu, Serret Mecanique and S.A.R.L. Devise. Address changes to VIT RESSORT from 'Chemin de Vignes, Veynes, 05400, France' to 'ZA le Boutariq, Rue du Pic de Bure, 05400 Veynes, France' and to CeramTech from 'Fabrikstrasse 23-29, Plochingen, 73207, Germany' to 'CeramTec GmbH, Medical Products Division, CeramTec Platz 1-9, 73207 Plochingen, Germany'

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