



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

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 13485:2016 & EN ISO 13485:2016 for the following scope:

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



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-04-25

Latest Revision Date: 2022-02-22

Effective Date: 2022-02-28

Expiry Date: 2022-08-27



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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](#).
Printed copies can be validated at 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	Sales administration
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 2797):

Gary E Slack, Senior Vice President Medical Devices

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

Date: **2021-05-12**

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.

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