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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

Digitally signed by Ceaicovschi Tudor
Date: 2022.06.30 14:56:45 EEST
Reason: MoldSign Signature
Location: Moldova

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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

Latest Revision Date: 2022-02-22

Effective Date: 2022-02-28

Expiry Date: 2022-08-27

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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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