

EC Certificate

For the Quality Assurance System
according the directive 93/42/EEC, Annex II
excluding section (4)



As a notified body of the European Union, DEKRA Certification GmbH certifies,
that the company

Amplitude S.A.S

11, Cours Offenbach • 26000 Valence, France

Certified locations:

11, Cours Offenbach • 26000 Valence, France
Porte du Grand Lyon • 01700 Neyron, France

applies a quality assurance system for the medical devices listed in the annex
according to the directive 93/42/EEC annex II. The approval is based on the result
of the re-certification audit report no. 50791-Z3-00, the decision dated 24.04.2012
and is only valid in connection with the successful performance of the annual
surveillance audits.

Date of the first
certification: 03.05.2002

This certificate is
valid until: 02.05.2017

Date of the last
recertification: 03.05.2012

Certificates
registration No.: 50791-16-04
English version

Stuttgart, 24.04.2012
DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany
Notified Body ID-number: 0124



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-992.94.16

Annex to the EC Certificate 50791-16-04 dated 2012-04-24

English version

Revision status: 1

Date: 2014-10-01

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Devices/device categories included in the certificate

Class II a:

- Instruments and accessories
- Markers
- Computer assisted surgery systems

Class II b:

- Osteosynthesis implants
- Accessories for hip joint replacements
- Accessories for knee joint replacements

Class III:

Hip joint replacements:

- INTEGRALE®, LOGIC® and GENERIC® femoral stems (DEV97-ET101)
- INTEGRALE® modular femoral stem (DEV97-ET130&131)
- INTEGRALE® and GENERIC® revision femoral stems (DEV06-ET102)
- INITIALE® modular first intention femoral stems and INITIALE® modular dysplastic femoral stems (DEV97-ET112)
- INITIALE® revision femoral stems (DEV06-ET112)
- ACOR® femoral stem and modular neck (DEV97-ET129&130)
- EXTREME® reconstruction femoral stem (DEV06-ET113)
- OPTIMAL® revision-reconstruction femoral stem (DEV06-ET130&137)
- INITIALE® femoral head (DEV13-ET112)
- M30NW metallic femoral head (DEV13-ET105)
- BIOLOX® Delta ceramic femoral head (DEV13-ET109)
- SATURNE® tripolar cup (DEV95/DEV96-ET114)
- EQUATEUR® acetabular cup (DEV96-ET103)
- INITIALE® acetabular cup (DEV96-ET110)
- SPHERIC® bipolar cup (DEV96-ET111)
- HORIZON® II acetabular cup and BIOLOX® Delta ceramic insert (DEV45-ET109)

