

CERTIFICATE

for Quality Management



DEKRA Certification GmbH hereby certifies that for

ALTATEC GmbH

Maybachstrasse 5 • 71299 Wimsheim, Germany

Scope:

Development and manufacturing of dental alloys dental implants
and appendant abutments, drills and instruments

Certified locations:

Maybachstrasse 5 • 71299 Wimsheim, Germany
Paul-Ehrlich-Straße 15 • 72076 Tübingen, Germany
Camlog Biotechnologies AG; Margarethenstraße 38 • 4053 Basel, Switzerland

EN ISO 9001:2008

by the decision dated 30.06.2009 and the report no. 50471-Z3-00,
proof of the introduction and application of a quality management system in
compliance with the above mentioned standards has been attained.

Date of the first
certification: 31.08.1999

This certificate is
valid until: 29.06.2014

Date of the last
recertification: 30.06.2009

Certificate-
registration No.: 50471-56-00
English version

DEKRA Certification GmbH
Stuttgart, 30.06.2009



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EN ISO 13485:2003 + AC:2007

by the decision dated 30.06.2009 and the report no. 50471-Z3-00,
proof of the introduction and application of a quality management system in
compliance with the above mentioned standards has been attained.

Date of the first
certification: 20.11.2002

This certificate is
valid until: 29.06.2014

Date of the last
recertification: 30.06.2009

Certificate-
registration No.: 50471-10-00
English version

DEKRA Certification GmbH
Stuttgart, 30.06.2009



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-992.00.02-46

CERTIFICATE

for the
Quality Assurance System



As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

ALTATEC GmbH
Maybachstrasse 5 • 71299 Wimsheim, Germany

Approval is based on the decision dated 30.06.2009 and the result of the report no. 50471-Z3-00 and is performed in accordance with the stipulations of

Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.



Date of the first certification: 31.08.1999

This certificate is valid until: 29.06.2014

Date of the last recertification: 30.06.2009

Certificate-registration No.: 50471-16-04
English version

DEKRA Certification GmbH
Stuttgart, 30.06.2009



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

Annex to the Certificate 50471-16-04 dated 30.06.2009

English version

Revision status: 0

Date: 30.06.2009

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Devices/device categories included in the certificate

Class II a:

- High-gold dental alloys and solders
- Dental abutments
- Screws for Dental abutments
- Healing caps for Dental implants
- Drills and Surgery sets for Dental implants

Class II b:

- Dental implants
- ALTApin set
- CorticoFix set



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