

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 17 03 76870 012

Manufacturer:

ALTATEC GmbH

Maybachstr. 5 71299 Wimsheim **GERMANY**

Facility(ies):

ALTATEC GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

ALTATEC GmbH

Paul Ehrlich Str. 15, 72076 Tübingen, GERMANY

Camlog Biotechnologies AG

Margarethenstraße 38, 4053 Basel, SWITZERLAND

04052768817266

CAMLOG Management GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

Product

Category(ies):

Medical devices supporting implant insertion, impression

taking and bonding

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713095093

Valid from:

2017-06-14

Valid until:

2019-06-29

2017-06-14 Date,

Stefan Preiß

1. Punil

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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