

Beglaubigte Fotokopie

EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

medical ins+inct®

Medical Instinct Deutschland GmbH

Graseweg 24
37120 Bovenden
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Dental implant systems, Prosthetic components and superstructures and Surgical instruments and drills, according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	456947 MR2
Certificate unique ID	170618481
Effective date	2015-03-19
Expiry date	2019-09-13
Frankfurt am Main	2015-03-19

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

Annex to Certificate
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Device family	Device	Class
Dental Implantat Systems	BoneTrust BoneTrust plus BoneTrust cone+ BoneTrust Sinus BoneTrust one BoneTrust mini	IIb
Prosthetic components and superstructures	Healing Abutments Impression Copings Esthetic Abutments Zirconium Dioxide Abutments Direct Abutments UCLA Abutments Scan Abutments Lucky Lock Abutments Retaining Screws	IIb
Surgical instruments and drills	BoneTrust Drilling Systems BoneTrust Instruments	IIa

Die vorstehende Fotokopie stimmt mit der mir vorliegenden Urschrift wörtlich überein.

Göttingen, den 17. April 2015



Dr. Bodenburg
Notar



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land: Bundesrepublik Deutschland.
Diese öffentliche Urkunde
 2. ist unterschrieben von Herrn Dr. Bodenburg
in Göttingen
 3. in seiner Eigenschaft als Notar
 4. sie ist versehen mit dem Siegel des Notars
Dr. Reinhard-Johannes Bodenburg in Göttingen
- Bestätigt:
5. in Göttingen
 6. am 20.04.2015
 7. durch den Präsidenten des Landgerichts
in Göttingen
 8. unter 910 E I 14265
 9. Siegel:
 10. Unterschrift:

I.V.

(Haacke)
Justizamtsinspektor

