



EC-CERTIFICATE



(Production quality assurance)

This is to certify that the company

anax dent GmbH

Olgastraße 120a 70180 Stuttgart Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

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

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Dental products according to annex

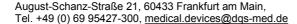
The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in 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. 251755 MR5
Certificate unique ID 170646932
Effective date 2016-04-08
Expiry date 2020-08-20
Frankfurt am Main 2016-04-08

DQS Medizinprodukte GmbH

Frank Graichen Managing Director

Dr. Thomas Feldmann Head of Certification Body









Annex to Certificate

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Device family	Device	Class
Temporary crown and bridge material	New Outline	lla
Bonding material for alloys and acrylics	Metal Bonder	lla
Non precious alloys	anax NPI	lla
Soldering paste	anax sold	lla
Precious alloys	anax-alloys	lla
Zirkonblancs for CAD/CAM technology	anax zirkonblancs	lla
Bonder for non precious alloys/Ceramic	anaxbond NP	lla
Lightcuring composite	Mock up direct / -flow anaxBLEND anaxGUM	lla Ila Ila
Fixation composite	base CEM ZR	lla
Dual-curing material	ViscoLC ViscoII	lla lla
Bonder	Zirkonbonder	lla
PMMA Blanks	Multi Blank/ Mono Blank	lla
Self-curing denture Based resin	Acryline	lla

