



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

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