



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



megadental GmbH

Seeweg 20
63654 Büdingen
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 materials, dental-alloys. Dental acrylics for individual dentures, orthodontic devices, otoplastic devices and temporary crowns and bridges. Metal resin bonding system, light curing contouring resin for dental applications as listed in the 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.	376505 MR2
Certificate unique ID	170536077
Effective date	2012-10-08
Expiry date	2015-07-08
Frankfurt am Main	2012-10-08

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

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-alloys	meganium <i>fm S</i>	Ila
	meganium <i>fm80</i>	Ila
	meganium <i>NF</i>	Ila
	meganium <i>CS</i>	Ila
Hot-Curing Resins	mega <i>CRYL HOT</i>	Ila
	mega <i>DON-N</i>	Ila
	mega <i>DON</i>	Ila
	mega <i>DON HI-IMPACT</i>	Ila
Cold-Curing Resins	mega <i>CRYL N</i>	Ila
	mega <i>CRYL S</i>	Ila
	mega <i>CRYL Gingiva</i>	Ila
	mega <i>CREATIV</i>	Ila
	mega <i>PRESS NV</i>	Ila
	mega <i>PRESS LV</i>	Ila
	mega <i>JET X</i>	Ila
	mega <i>TRIM Provi Implant</i>	Ila
	mega <i>SIN ORTHO</i>	Ila
	mega <i>SIN ORTHO DE</i>	Ila
	mega <i>Farbkonzentrat</i>	Ila
	mega <i>DUR</i>	Ila
	Light-Curing Resins	mega <i>GEN LC</i>
mega <i>GEN LC Paste</i>		Ila
mega <i>PinkOpak LC</i>		Ila