



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

GDF Gesellschaft für dentale Forschung und Innovationen GmbH

Dieselstr. 5-6
61191 Rosbach
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 devices 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.	230469 MR2
Certificate unique ID	170703821
Effective date	2018-10-12
Expiry date	2023-10-11
Frankfurt am Main	2018-10-12

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
Certificate registration No.: 230469 MR2
Certificate unique ID: 170703821
Effective date: 2018-10-12

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Device family	Device	Class
Dental devices	Resin based dental colors	IIa
	Denture base materials	IIa
	Temporary crown and bridge materials	IIa
	Dental filling materials on composite basis	IIa
	Resin facing material	IIa
	Light-curing denture lacquer	IIa
	Dentin bonding	IIa
	Dental bleaching gel	IIa
	Fixing composite / root pin cement	IIa
	Stump build-up material	IIa
	Ceramic repair material	IIa
	Attachment glue	IIa
	Dental etching gel	IIa
	Glass fibres with light curing resin matrix	IIa
	Fixing composite for brackets	IIa
	Dentin and enamel adhesives	IIa
	Dental colors for individualization	IIa
	Frame work covering material	IIa
	Bonding agent	IIa
	Millable CAD / CAM materials	IIa
Orthodontic bonding agent	IIa	