



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

FMZ GmbH

Charles Darwin Ring 3a
18059 Rostock
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 implants sterile, Drill non sterile, Implants abutments extraline non sterile, Implants abutments extraline sterile, Dental Implants steril and Thread Drill non sterile

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.	204456 MR2
Certificate unique ID	170725820
Effective date	2018-09-21
Expiry date	2019-11-10
Frankfurt am Main	2018-09-21

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
Implants abutments <i>extraline</i> sterile	easyfixbase® abutments (angulation concept)	IIb
Fixing units sterile	fixing unit for dental stencils	IIa
Esthetic® Dental Implants sterile (DUOTex® Surface)	Silver, Gold, Mini, Platinum	IIb
Biokom Dental Implants sterile (DUOTex® Surface)	Biokom	IIb
Thread Drill non sterile	Silver, Gold	IIa