



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

Mblen

Sigrid Uhlemann Managing Director

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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.: 204456 MR2 Certificate unique ID: 170725820 Effective date: 2018-09-21

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Device family	Device	Class
alphatech[®] Dental implants sterile	Tube-Line VTPS-BONIT® Tube-Line BONITex® Uni-Line VTPS- BONIT® Slim-Line BONITex®	111
	Tube-Line VTPS Tube-Line DUOTex [®] Uni-Line VTPS Slim-Line DUOTex [®]	llb
Drill non sterile	universal drill finisher round drill corticalis-drill 2,0mm-bone drill 2,8mm-bone drill trephine bur pilot drill 2mm bone drill Slim-Line 3-cant bone drill Slim-Line	lla
Implants abutments <i>extraline</i> non sterile	provisional abutment standard abutment angled abutment titanium 10° angled abutment titanium 20° telescopic abutment ball abutment aesthetic ceramic abutment bar abutment titanbase gingival former castable abutment fixator 1 and 2 healing cap bonding base angulation concept (Integral parts of the 0° abutment ZrN coated) caps (Slim-Line) multi-abutment	lla
	P-Switch Abutment Kobold Abutment cover screw special cover screw bar screw	
	osteosynthesis screw abutment screw alpha-loc	llb







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Device family	Device	Class
Implants abutments extraline sterile	easyfixbase [®] abutments (angulation concept)	llb
Fixing units sterile	fixing unit for dental stencils	lla
Esthetic® Dental Implants sterile (DUOTex [®] Surface)	Silver, Gold, Mini, Platinum	llb
Biokom Dental Implants sterile (DUOTex [®] Surface)	Biokom	llb
Thread Drill non sterile	Silver, Gold	lla

