



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Dürr Dental AG

Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
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:

Disinfectants for invasive medical devices, disinfectants for non-invasive medical devices, disinfection devices, cannulas, image memory, fluoroscopy, data management system, Image data archiving and transmission system, compressors for dental medical applications, scaler ultrasound and dental hand instrument accordance with 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.	518373 MR2
Certificate unique ID	170626590
Effective date	2015-07-26
Expiry date	2020-06-28
Frankfurt am Main	2015-07-26

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
Disinfectants for invasive medical devices	Instrument disinfectants ID 212, ID 213, ID 220	IIb
	Surface disinfectant FD 320, FD 322, FD 333, FD 350, FD 366 sensitive	IIb
	Impression Disinfectants MD 520	IIb
	RinsEndo Disinfectant	IIb
	Vector Disinfectant	IIb
Disinfectants for non-invasive medical devices	Surface disinfectant FD 300 top wipes	IIa
	Suction machines disinfectants Orotol, Orotol Plus, Orotol Ultra	IIa
	Spittoon disinfectants MD 550	IIa
	cleaning Wipes, Image plate cleaning wipes	IIa
Disinfection devices	Hygoclave 90	IIb
	Hygojet	IIa
Cannulas	Universal-/Reflux/Prophylaxe-/children-kanülen	IIa
	Surgical suction	IIa
Image memory, Fluoroscopy	Image Plates	IIa
Data management system	DBS Win	IIa
Image data archiving and transmission system	VistaRay	IIa
Compressors for dental medical applications	Tornado 1	IIa
	Tornado 2	IIa
	Tornado 4	IIa
	Duo	IIa
	Duo Tandem	IIa
	Trio	IIa
	Quattro	IIa
	Quattro Tandem	IIa
	P-Reihe	IIa
Scaler ultrasound	Vector	IIa
Dental hand instrument, endodontic	RinsEndo	IIa